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(71) Applicant: STANFORD SURGICAL TECHNOLOGIES, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).

(72) Inventors: STERMAN, Wesley, D.; 2121 Sacramento Street #604, San Francisco, CA 94109 (US). GARRISON, Michi, E.; 2325 Casa Bona Avenue, Belmont, CA 94002 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). STEVENS, John, H.; 727 East Loma Verde Avenue, Palo Alto, CA 94303 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend Khourie and Crew, 20th floor, One Market Plaza, Steuart Street Tower, San Francisco, CA 94105 (US).

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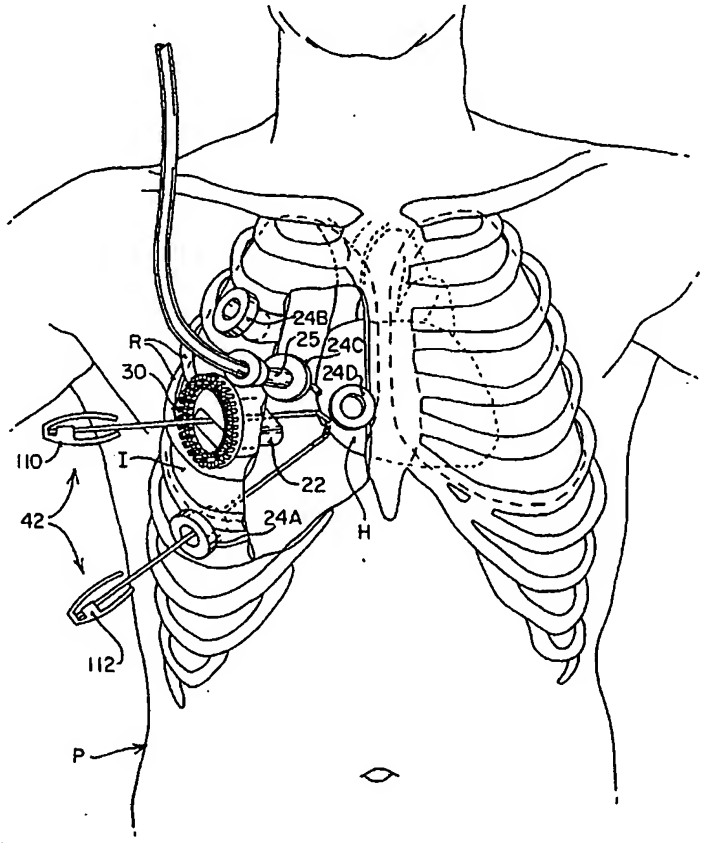
(57) Abstract

The invention provides devices and methods for performing less invasive surgical procedures with an organ or vessel. One embodiment provides a method of closed chest surgical intervention within an internal cavity of a patient's heart. The patient's heart is arrested and cardiopulmonary by-pass is established. A scope (25) extending through a percutaneous intercostal penetration in the patient's chest is used to view an internal portion of the patient's chest. The penetration is formed in a wall of the heart using a cutter (110) introduced through the percutaneous penetration. An interventional tool is then introduced through a cannula (22) positioned in the penetration. The interventional tool is inserted through the penetration to perform a surgical procedure within the internal cavity under visualization by a scope (25). A cutting tool is introduced into the patient's left atrium from a right portion of the patient's chest to remove the patient's mitral valve. A replacement valve (36) is then introduced through the intercostal space and through the penetration in the heart, and the replacement valve is attached in the mitral valve position.



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DEVICES AND METHODS FOR INTRACARDIAC PROCEDURES

FIELD OF THE INVENTION

This invention relates generally to instruments and techniques for performing less-invasive surgical procedures, and more specifically, to instruments and techniques for less-invasive surgery within the heart and great vessels.

BACKGROUND OF THE INVENTION

Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the

surgical team may directly visualize and operate upon the heart and other thoracic contents.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the

valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, *Replacement Cardiac Valves* 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, *Cardiac Surgery* 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position accessible through the sternotomy. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the forementioned techniques may then be used to repair or replace the valve.

An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed

in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

What is needed, therefore, are devices and methods for carrying out heart valve repair and replacement as well as other procedures within the heart and great vessels that reduce the trauma, risks, recovery time and pain that accompany current techniques. The devices and methods should facilitate surgical intervention within the heart or great vessels without the need for a gross thoracotomy, preferably through small incisions within intercostal spaces of the rib cage, without cutting, removing, or significantly deflecting the patient's ribs or sternum. In particular, the devices and methods should allow for removal of tissue from the thoracic cavity, as well as for introduction of surgical instruments, visualization devices, replacement valves and the like into the thoracic cavity, to facilitate heart valve repair and replacement. Preferably, the devices and methods should facilitate replacement of a heart valve with various types of prostheses, including

mechanical and biological prostheses, homografts, and allografts.

SUMMARY OF THE INVENTION

The invention provides devices and methods for performing less-invasive surgical procedures within an organ or vessel, and particularly, within the heart and great vessels of the thoracic cavity. The devices and methods of the invention facilitate intervention within the heart or great vessels without the need for a median sternotomy or other form of gross thoracotomy, substantially reducing trauma, risk of complication, recovery time, and pain for the patient. Using the devices and methods of the invention, surgical procedures may be performed through percutaneous penetrations within intercostal spaces of the patient's rib cage, without cutting, removing, or significantly displacing any of the patient's ribs or sternum. The devices and methods are particularly well-adapted for heart valve repair and replacement, facilitating visualization within the patient's thoracic cavity, repair or removal of the patient's natural valve, and, if necessary, attachment of a replacement valve in the natural valve position. The invention facilitates valve replacement with any of a variety of commercially-available replacement valves, including mechanical prostheses, bioprostheses, homografts, and allografts.

In a first preferred embodiment, the invention provides a method of closed-chest surgical intervention within an internal cavity of the patient's heart or great vessel. Utilizing the method of the invention, the patient's heart is arrested and cardiopulmonary bypass is established. An internal portion of the patient's chest is viewed by means of a scope extending through a percutaneous intercostal penetration in the patient's chest. A cutting means is introduced through a percutaneous intercostal penetration in the patient's

chest, and the cutting means is used to form an internal penetration in a wall of the heart or great vessel. An interventional tool is then introduced through a percutaneous intercostal penetration and through the internal penetration in the heart or great vessel to perform a surgical procedure within the internal cavity under visualization by means of the scope. One or more percutaneous cannulae may be positioned within an intercostal space of the chest wall through which the interventional tool may be introduced into the chest cavity. The surgical procedures which may be performed within the heart or great vessel include repair or replacement of heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, myocardial drilling, correction of congenital defects, coronary artery bypass grafting, and other procedures.

The patient's heart is preferably arrested by occluding the patient's aorta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter. Cardioplegic fluid is then introduced through a lumen in the catheter into the patient's aorta upstream of the expandable member to arrest cardiac function. Alternatively, or in addition to such antegrade cardioplegic fluid delivery, cardioplegic fluid may be delivered in a retrograde manner by means of a catheter positioned in the coronary sinus of the patient's heart. In an alternative approach, an external cross-clamp may be placed thoracoscopically on the aorta through a small incision or cannula in the patient's chest. Cardioplegic fluid may be delivered through either a thoracoscopically introduced cannula or an endovascular catheter extending into the ascending aorta upstream of the cross-clamp.

In a preferred embodiment, the surgical procedure comprises surgically treating a heart valve. Such surgical treatment may involve repairing the valve by introducing instruments through an intercostal penetration and through the internal penetration in the heart to perform, for example, annuloplasty, quadrangular resection of valve leaflets, commissurotomy, reattachment of chordae tendonae or papillary muscle tissue, shortening of chordae tendonae, decalcification, and the like.

The heart valve may also be replaced with a replacement valve. In this embodiment, the method may further comprise the step of removing all or part of the patient's natural heart valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration in the heart. The method further comprises the step of introducing a replacement valve through a percutaneous intercostal penetration and through the internal penetration into the internal cavity within the heart. The replacement valve is then fastened within the heart, usually by means of an instrument introduced through a percutaneous intercostal penetration and through the internal penetration in the heart wall.

The method may further include the step of sizing the patient's heart valve before the replacement valve is introduced. In an exemplary embodiment, a sizing instrument is introduced through a percutaneous intercostal penetration and through the internal penetration in the heart to measure the size of the valve annulus and to determine the size of the replacement valve.

The replacement valve may be fastened in position in various ways, including suturing the replacement valve to an annulus at the natural valve position in the heart. In one embodiment, the sutures are applied to the annulus at the valve position, drawn out of the patient's body

through the internal penetration and through a percutaneous intercostal penetration, and then applied to the replacement valve. The sutures may further be radially arranged in spaced-apart locations about an organizer ring disposed outside of the patient's body. The sutures are then held in tension as the replacement valve is introduced into the interior of the heart and positioned in the natural valve position. The replacement valve may be introduced by means of a valve holder attached to an elongated handle, or simply pushed along the sutures by means of the surgeon's hands or conventional tools such as forceps or needle drivers.

In a particular preferred embodiment, the heart valve comprises a mitral valve which is disposed between the left atrium and left ventricle of the patient's heart. A percutaneous penetration is made within an intercostal space in a right lateral portion of the patient's chest, usually within the fourth, fifth, or sixth intercostal space. From this penetration, an internal penetration may be formed in the wall of the left atrium at a location which is in a generally straight line drawn from the penetration in the right lateral portion of the chest to the patient's mitral valve. In this way, surgical instruments may be introduced from the penetration in the right chest to form the internal penetration in the heart wall, repair or excise the patient's natural valve, and introduce and attach a replacement valve.

In a further aspect of the invention, a prosthesis assembly is provided for closed-chest replacement of a heart valve. The prosthesis assembly comprises a replacement valve having an annular attachment portion and a movable valve portion coupled to the attachment portion. The prosthesis assembly further includes holder means releasably mounted to the attachment portion, wherein the holder means is configured to allow

introduction of the replacement valve through an intercostal space in the patient's chest.

In a preferred embodiment, the replacement valve and the holder means together have a profile with a width which is less than the width of the intercostal space. Preferably, the intercostal space is less than about 20 mm in width. The attachment portion of the replacement valve will usually have an outer diameter which is greater than the intercostal width.

The holder means of the device preferably comprises an elongated handle having a distal end mounted to the replacement valve and a proximal end opposite the distal end. The handle is configured to introduce the replacement valve into the patient's heart through the intercostal space. Preferably, the handle is at least about 20 cm in length to allow positioning the replacement valve in the heart from a right lateral portion of the patient's chest. The handle may further include means for releasing the replacement valve, the releasing means being configured for actuation from the proximal end of the handle.

The handle may also include means for pivoting the replacement valve from a first orientation for introduction through the intercostal space to a second orientation for attachment in the patient's heart. The pivoting means is configured for actuation from a proximal end of the handle. In this way, the replacement valve may be introduced edge-first through the intercostal space, then pivoted about an axis generally perpendicular to the handle into an orientation suitable for attachment within the patient's heart.
Alternatively, the valve prosthesis may be collapsible or compressible to permit introduction through an intercostal space into the thoracic cavity.

Preferably, the replacement valve is premounted to the holder means and the two are sterilized and packaged together in a sterile pack. In this way, the pack may be

opened in the sterile operating room environment with the valve and holder ready for immediate surgical use.

In a further embodiment, the invention provides a thoracoscopic device for placement of a replacement valve in a valve position of a patient's heart. In a preferred embodiment, the thoracoscopic device comprises an elongated handle configured for positioning through an intercostal space in the patient's chest, as described above. The device includes means at a distal end of the handle for releasably holding a replacement valve in an orientation for introduction through the intercostal space, and may further include means for pivoting the replacement valve relative to the handle from a first orientation for introduction through the intercostal space, to a second orientation for placement in the valve position. The thoracoscopic device further includes, in a preferred embodiment, means at the proximal end of the handle for releasing the replacement valve from the holding means once the prosthesis has been positioned and secured within the heart.

In a further aspect of the invention, a percutaneous access cannula is provided to facilitate closed-chest replacement of a heart valve in a patient's heart. The access cannula comprises a cannula body configured for placement in an intercostal space in the patient's chest, the cannula having a distal end, a proximal end, and a lumen extending therebetween. The lumen is configured to allow passage of a replacement valve therethrough. An obturator is positionable in the lumen to facilitate introduction of the cannula body. The obturator has a cross-sectional width that is equal to or less than the width of the intercostal space, and a cross-sectional height that is greater than the cross-sectional width.

The replacement valve has an annular attachment portion with an outer diameter, and the obturator as well as the lumen in the cannula have a cross-sectional height at least equal to the outer diameter, allowing the

replacement valve to be introduced through the lumen of the cannula. In one embodiment, the cross-sectional height of the lumen in the cannula is about two to six times the cross-sectional width. The lumen and obturator may have a rectangular cross-section, oval cross-section, or other shape. The cannula body may be rigid or deformable, while the obturator is usually rigid to facilitate introduction.

The access cannula may further be provided with suture retaining means on its proximal end configured to retain a plurality of sutures in a spaced-apart relationship. The suture retaining means may have various configurations, such as a plurality of slots in a proximal end of the cannula body in circumferentially spaced positions around the lumen. The slots in the access cannula may further include means such as slitted, elastomeric inserts, for frictionally engaging the sutures to maintain tension thereon while the prosthesis is introduced into the heart.

A second organizing ring may also be provided in a position spaced-apart from the access cannula outside of the patient's body. The second organizing ring has an interior passage through which the sutures may extend and a plurality of means circumferentially spaced around the passage for frictionally engaging the sutures. In this way, sutures may be applied to the valve annulus in the patient's heart, drawn through the lumen in the cannula and retained in the suture organizing means on the access cannula's proximal end. The sutures may then be applied to the replacement valve and retained in the second organizing ring. Once all of the sutures have been applied to the prosthesis, the prosthesis may be introduced into the heart by sliding it along the sutures, which are held in tension by the second organizing ring. Alternatively, the sutures may be held in tension by individual clamps, tape, commercially-available suture organizers, or other means

for exerting traction on the free ends of each individual suture.

The invention further provides a system for closed-chest replacement of a heart valve in a patient's heart. The system includes means for forming a percutaneous intercostal penetration in the patient's chest, and a visualization scope configured to pass through an intercostal space in the patient's chest for viewing an internal chest cavity. Means are also provided for arresting the patient's heart from a location outside of the chest cavity. A cardiopulmonary bypass system, including means for delivering oxygenated blood to the patient's arterial system, is provided for maintaining peripheral circulation of oxygenated blood. Cutting means positionable through a percutaneous intercostal penetration into the chest cavity are provided for forming an internal penetration in a wall of the patient's heart or great vessel. The system further provides interventional means positionable through a percutaneous intercostal penetration and through the internal penetration for performing a surgical procedure within the heart or great vessel.

In a preferred embodiment, the means for arresting the heart comprises an endovascular catheter having expandable means near its distal end for occluding the patient's ascending aorta between the patient's coronary arteries and the patient's brachiocephalic artery. The catheter further includes an internal lumen for delivering cardioplegic fluid into the aorta upstream of the expandable means to perfuse the myocardium through the coronary arteries.

The interventional means preferably comprises means for securing a replacement valve in a valve position within the patient's heart. Usually, the replacement valve securing means comprises an elongated handle like that described above, having means at its distal end for releasably holding a replacement valve. The handle may

also facilitate pivoting the replacement valve for introduction through an intercostal space.

Preferably, the system also includes at least one cannula positionable in a percutaneous intercostal penetration, through which surgical instruments or a replacement valve may be introduced into the thoracic cavity. The cannula may have a lumen with a cross-sectional height greater than its width to allow edge-first introduction of a replacement valve that has an outer diameter larger than the intercostal space, as described above.

The system may further include cutting means positionable through a percutaneous intercostal penetration and through the internal penetration in the patient's heart for removing at least a portion of the patient's heart valve. The cutting means for removing the heart valve may comprise scissors, retractable knife, biters, or the like.

The system preferably includes means positionable through a percutaneous intercostal penetration and through the internal penetration for sizing an annulus of the patient's heart valve. In one embodiment, the sizing means comprises an elongated shaft and a plurality of interchangeable sizing disks of various sizes attachable to a distal end of the shaft. The shaft and sizing disk may be introduced through a percutaneous intercostal penetration and through the internal penetration to position the sizing disk adjacent to the annulus of the patient's heart valve, allowing a comparison of the annulus diameter to the disk diameter. The sizing disk may be pivotable relative to the shaft to allow introduction into the thoracic cavity through an intercostal space. Alternative means for sizing may also be used, such as expandable baskets, balloons, endoscopic or endovascular visualization, fluoroscopy, or transesophageal echocardiography.

The system may further include means for attaching the replacement valve to the patient's heart, which comprises, in one embodiment, means for suturing the replacement valve to a valve annulus in the patient's heart. The system preferably includes organizing means for maintaining the sutures in spaced-apart positions outside of the chest cavity after the sutures have been